

SUMMARY OF SAFETY AND EFFECTIVENESS**1.0 Submitted By:**

Annette Hellie
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2.0 Date Submitted

September 7, 2000

3.0 Device Name(s):**3.1 Proprietary Names**

Paragon CZE® 2000 Clinical Capillary Electrophoresis System
Paragon CZE 2000 Capillary Electrophoresis Buffer-100

3.2 Classification Names

Immunofixation Electrophoresis – Class II; Special Controls
[Immunoelectrophoretic Immunoglobulins (G, A, M)
21 CFR § 866.5510]

4.0 Legally Marketed Device

The Paragon CZE 2000 Capillary Electrophoresis System and Buffer-100 claims substantial equivalence to the Paragon CZE 2000 Capillary Electrophoresis System and reagents currently in commercial distribution.
FDA 510(k) Number K953077

5.0 Device Description

Electrophoresis is a basic clinical technique for separating protein fractions in serum. In capillary electrophoresis the separation of proteins occurs in an uncoated fused silica capillary. Capillary electrophoresis utilizes two main principles in the separation of proteins. First, at alkaline pH, a strong electroosmotic flow (EOF) is created. The EOF is the overall fluid movement of positively charged buffer ions carrying fluid toward the cathode. Secondly, the electrophoretic migration of the individual proteins is based on their isoelectric point, tertiary structure, and differences in their charge to mass ratio at specific voltage, electrolyte composition, and pH conditions.

6.0 Intended Use

The Paragon CZE® 2000 Clinical Capillary Electrophoresis System used in conjunction with Paragon CZE 2000 SPE Reagents and currently marketed controls, is intended for use in the separation and measurement of protein fractions in human serum. The Paragon CZE 2000 Clinical Capillary Electrophoresis System used in conjunction with the Paragon CZE 2000 IFE/s Reagents and Paragon CZE 2000 IFE/s Control is intended for use in the immunological identification of monoclonal components in human serum.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The Paragon CZE® Capillary Electrophoresis System and Buffer have been modified in order to improve recognition of monoclonal components. This has been accomplished through a formulation change to the Buffer-100 reagent and associated software changes. There are no changes to the IFE/s instructions for use. New labels have been produced for the buffer reagent.

8.0 Summary of Performance Data

Performance of the modified buffer



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT - 5 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Annette Hellie
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Box 8000
Brea, California 92822-8000

Re: K002799
Trade Name: Paragon CZE® 2000 Capillary Electrophoresis System and Buffer-100
Regulatory Class: II
Product Code: CFF
Dated: September 7, 2000
Received: September 8, 2000

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

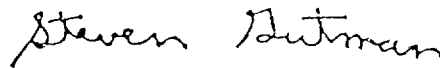
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

page 1 of 1

510(k) Number (if known):

Device Name: **Paragon CZE® 2000 Capillary Electrophoresis System and Buffer-100**

Indications for Use:

The Paragon CZE® 2000 Clinical Capillary Electrophoresis System used in conjunction with Paragon CZE 2000 SPE Reagents and currently marketed controls, is intended for use in the separation and measurement of protein fractions in human serum. The Paragon CZE 2000 Clinical Capillary Electrophoresis System used in conjunction with the Paragon CZE 2000 IFE/s Reagents and Paragon CZE 2000 IFE/s Control is intended for use in the immunological identification of monoclonal components in human serum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____
Optional Format 1-2-96

Teronica J. Calvin for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number *K002799*